UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,743	01/17/2006	Takashi Maeda	01997.0266	1520

22852 7590 01/04/2007

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER	
SPIVACK, PHYLLIS G	
ART UNIT	PAPER NUMBER
1614	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/564,743	MAEDA ET AL.	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4 and 8-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 4, 8-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicants' amendment filed October 18, 2006 is acknowledged. Claims 2, 3 and 5-7 are canceled. New claims 8-13 are presented. Accordingly, claims 1, 4 and 8-13 are now under consideration.

The objection to claim 3 under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim, is moot subsequent to the cancellation of the claim.

Claims 1, 3, 4, 6 and 7 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Claims 3, 6 and 7 are canceled.

The rejection of record under 35 U.S.C. 112, second paragraph, is withdrawn following the deletion of the term "general", and the recitations "at least one selection from the group consisting of", "which may have 1 to 3 alkoxy groups" and "which may have 1 to 3 carboxyl groups".

Claims 1, 4 and 8-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

The recitation in claims 1 and 4 "wherein an amount of the enema preparation is one tenth as much as the amount used with oral administration" is indefinite. It is unclear whether or not the "amount" refers to the active agent, 6-[2-(3,4-diethoxyphenyl)thiazol-4-yl]pyridine-2-carboxylic acid, or the amount of the preparation.

Clarification is required.

Claims 4-7 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11 and 12 of U.S. Patent No. 6,291,487 in the last Office Action. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 12 in the patent recites the same compound as presently recited in claims 5 and 7 for use in the treatment of Crohn's disease, an inflammatory bowel disease. Intrarectal administration is disclosed in column 10, lines 19-20.

Claims 1-3 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of copending Application No. 10/424904. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 4-6 in the co-pending application recite the same compound as instant claim 2. On page 23 of the specification of the co-pending application, intrarectal administration is taught. Applicants are not entitled to procure claims based on discovery that known compositions can be adapted to new uses.

Applicants argue the present invention drawn to an enema preparation, as now set forth in claims 1 and 4, can reduce the amount of the claimed thiazole compound or a salt thereof to such an extent that the skilled artisan could not conceive from commercially available drugs.

It is unclear whether or not the "amount" refers to the active agent, 6-[2-(3,4-diethoxyphenyl)thiazol-4-yl]pyridine-2-carboxylic acid, or the amount of the preparation.

Accordingly, the rejections previously (provisionally) set forth on the ground of nonstatutory obviousness-type double patenting, are maintained.

Claims 1-7 were rejected in the last Office Action under 35 U.S.C. 102(b) as being anticipated by Banan et al., Free Radical Biology & Medicine. It was asserted Banan teaches local administration of the compound OPC-6535, 6-[2-(3,4-diethoxyphenyl)thiazole-4-yl]pyridine-2-carboxylic acid, for use in the treatment of inflammatory bowel diseases, such as ulcerative colitis. The compound protects gastrointestinal mucosal integrity against reactive oxygen metabolites (ROM).

Applicants argue Banan's disclosure refers to possible administration routes for the ODC compound.

Applicants' arguments are not found persuasive because Banan teaches either a systemic (oral) or local (enema) administration of OPC. One skilled in the art would have been motivated to administer ODC through local administration because Banan teaches the local administration of ODC could effectively scavenge oxidants produced at the basolateral or apical side of epithelial cell monolayers. See column two on page 296 where enema administration is disclosed to prevent the disruption of human intestinal barrier function.

The rejection of claims 1 and 4 under 35 U.S.C. 102(b) as being anticipated by Banan et al., Free Radical Biology & Medicine, is maintained.

Applicants' arguments with respect to claims 1-7 that were rejected under 35 U.S.C. 103(a) as being unpatentable over Chihiro et al., U.S. Patent 6,291,487, in the

last Office Action, have been considered but are moot in view of the new ground of rejection.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 4 and 8-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chihiro et al., U.S. Patent 6,291,487, in view of Remington's Pharmaceutical Sciences.

Chihiro teaches the administration of 6-[2-(3,4-diethoxyphenyl)thiazole-4-yl]pyridine-2-carboxylic acid for use in the treatment of the inflammatory bowel disease, Crohn's disease. Intrarectal administration is disclosed in column 10, lines 19-20. Enema administration is conventional practice in the treatment of Crohn's disease. Although Chihiro fails to teach enema formulations, Remington teaches the preparation of enema formulations with both aqueous and nonaqueous solvent systems. See page 144, column 2, where water is employed to dissolve the active agent. See column 2 on page 1803, where oil solutions are used as nonaqueous solvents. Because oxidative inflammatory intestinal disorders are characterized by an abnormal mucosal barrier, one skilled in the gastroenterology art would have been motivated to prepare and administer an enema preparation. Such would have been obvious in the absence of evidence to the contrary because it would have been reasonable to expect an enema formulation

comprising a known efficacious drug for the treatment of Crohn's disease to provide a local beneficial affect to the disease process. The determination of an optimal concentration of the active drug entity is a parameter that is well within the purview of those skilled in the art through no more than routine experimentation.

No claim is allowed.

Applicants' Amendment necessitated the new grounds of rejection presented in this Office Action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this Final Action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached on 10:30 AM-7 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ardin Marschel, may be reached on 591-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phyllis Spivack

December 26, 2006

Phyllis G. Spivack

PHYLLIS SPIVACK
PRIMARY EXAMINER